

Applicants : Yasuaki Ogawa et al.
For : PROTEIN SUSTAINED-RELEASE MICROPARTICLE
PREPARATION FOR INJECTION AND PROCESS FOR
PRODUCING THE SAME
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In the Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Original) A protein drug sustained-release microparticle preparation for injection, characterized by comprising a porous apatite or derivative thereof containing a protein drug, coated with or adhered to, an *in vivo* disappearing polymer.
2. (Original) The protein drug sustained-release microparticle preparation for injection according to claim 1, characterized in that the *in vivo* disappearing polymer is a block copolymer consisting of polyethylene glycol and polylactic acid or copolylactic-glycolic acid.
3. (Original) The protein drug sustained-release microparticle preparation for injection according to claim 2, characterized in that the block copolymer consisting of polyethylene glycol and polylactic acid or copolylactic-glycolic acid is a block copolymer consisting of polylactic acid or copolylactic-glycolic acid-polyethylene glycol-polylactic acid or copolylactic-glycolic-acid.
4. (Original) The protein drug sustained-release microparticle preparation for injection according to claim 2, characterized in that the block copolymer consisting of polyethylene glycol and polylactic acid or copolylactic-glycolic acid has a weight-average molecular weight of 3,000 to 20,000.
5. (Currently Amended) The protein drug sustained-release microparticle preparation for injection according to claim 2 ~~or 3~~, characterized in that the block copolymer consisting of polyethylene glycol and polylactic acid or copolylactic-glycolic acid has 20 to 90% by weight of polyethylene glycol.

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6. (Original) The protein drug sustained-release microparticle preparation for injection according to claim 1, characterized in that the porous apatite or derivative thereof contains a protein drug and a divalent metal salt.
7. (Original) The protein drug sustained-release microparticle preparation for injection according to claim 1, characterized in that the porous apatite or derivative thereof has a protein drug content of 5 to 30%.
8. (Original) The protein drug sustained-release microparticle preparation for injection according to claim 1, characterized in that the porous apatite or derivative thereof has an average particle size of 0.5 to 30 μm .
9. (Original) The protein drug sustained-release microparticle preparation for injection according to claim 1, characterized in that the porous apatite or derivative thereof is treated in the range from 100 to 600°C.
10. (Original) The protein drug sustained-release microparticle preparation for injection according to claim 1, characterized in that the porous apatite or derivative thereof is an apatite derivative in which a portion of calcium in the porous apatite is substituted with zinc.
11. (Original) A process for producing a protein drug sustained-release microparticle preparation for injection, characterized by comprising dispersing microparticles of a porous apatite or derivative thereof in an aqueous solution of a protein drug, stirring the dispersion, dispersing the resulting powder in an aqueous solution or suspension of a biodegradable polymer, stirring the dispersion, and then freeze drying or vacuum drying to give a powder.

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12. (New) The protein drug sustained-release microparticle preparation for injection according to claim 3, characterized in that the block copolymer consisting of polyethylene glycol and polylactic acid or copolylactic-glycolic acid has 20 to 90% by weight of polyethylene glycol.